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This progress report covers the third year of existence of the Center for Prostate Disease Research (CPDR), a collaborative research program of the Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Medical Center (WRAMC) and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology (AFIP). The Center is involved in the study of the molecular biology of prostate disease through laboratory activities at USUHS and the clinical study of prostate patients and pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both basic and clinical study of prostate cancer to bring basic science advances to the clinical benefit of prostate cancer patients.

During this report, period the CPDR has made a number of important scientific advancements related to clinical and basic science studies of prostate cancer. The clinical database of DoD prostate cancer patients has grown to over 2,500 cases and has been used for important studies. Most notably, we have discovered that African American prostate cancer patients have higher prostate specific antigen (PSA) levels due primarily to larger primary tumor size. This work was published this year in a feature article in The Journal of the American Medical Association. The database continues to expand and will provide outstanding ongoing clinical research opportunities. The basic science laboratory program has also excelled. The p53 tumor suppressor gene activation has been characterized in prostate cancer, been found to be an important prognostic marker in early stage disease treated by surgery, and formed the basis for exciting pre-clinical studies of p53-adenovirus gene therapy. Other gene alterations including bcl-2, p16, and androgen receptor have been studied in prostate cancer and many ongoing molecular investigations are in progress.

Overall, the CPDR is becoming recognized as a world-class prostate cancer research program and is providing positive recognition for WRAIR, USUHS, WRAMC, AFIP, and the USAMRMC.

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20 DEC 95

PI - Signature Date

TABLE OF CONTENTS

TITLE: Support of the Center for Prostate Disease Research at the Walter Reed Army Institute of Research

I. INTRODUCTION/SUMMARY STATEMENT

This progress report covers the third year of existence of the Center for Prostate Disease Research (CPDR), a collaborative research program of the Uniformed Services University of the Health Sciences (USUHS), the Walter Reed Army Medical Center (WRAMC) and Institute of Research (WRAIR), and the Armed Forces Institute of Pathology (AFIP). The Center is involved in the study of the molecular biology of prostate disease through laboratory activities at USUHS and the clinical study of prostate patients and pathology of the prostate at WRAMC and AFIP. The main goal of CPDR is to integrate both basic and clinical study of prostate cancer to bring basic science advances to the clinical benefit of prostate cancer patients.

The CPDR laboratory is housed in rooms A-3009 & A-3018 and contains approximately 1,500 sq. ft. of space within the Department of Surgery at USUHS and is a fully-equipped molecular biology laboratory. Five full-time researchers and several part-time

research students are utilizing this facility. The CPDR laboratory is also being utilized for training of Urology residents from Walter Reed in the field of molecular biology of prostate cancer. A formal memorandum of understanding for the National Naval Medical Center, Bethesda, MD, to participate in these efforts has been completed. CPDR clinical activities are based at the Urology Service, Department of Surgery at WRAMC. Three 150 sq. ft. offices houses five full-time employees and a number of part-time researchers. A comprehensive clinical database of all prostate cancer patients treated at WRAMC is underway which is integrated with pathologic and molecular studies.

II BODY

a) Personnel

NAME	FUNDING SOURCE	START DATE	STOP DATE	FT/PT	JOB DESCRIPTION
Judd W. Moul, LTC, MC	Military	09/14/92	NA	FT	Director, CPDR
David G. McLeod, COL, MC	Military	09/14/92	NA	FT	Chief of Urology, WRAMC
Norman M. Rich, MD	USUHS	09/14/92	NA	PT	USUHS Senior Consultant
Sherry S. Osborne	USUHS	09/14/92	NA	PT	USUHS Administrator
Donald Sturtz, MD	USUHS	09/15/94	NA	PT	USUHS Consultant
F.K. Mostofi, MD	AFIP	09/14/92	NA	PT	Pathologist
Isabell A. Sesterhenn, MD	AFIP	09/14/92	NA	PT	Pathologist
Shiv K. Srivastava, PhD	HJF	05/01/93	NA	FT	Director, CPDR Laboratory
Jaya Gaddipati, PhD	HJF	10/01/93	NA	FT	Molecular Biologist
Dorothy Tong	HJF	05/01/94	8/1/95	FT	Molecular Biologist
Juli Harris, BA	HJF	10/01/93	9/4/95	FT	Clinical DBase Coordinator
Rene Mooneyhan, BA	HJF	06/20/94	NA	FT	Clinical DBase Researcher
Shirley L. Craig	HJF	05/09/94	NA	FT	Administrative Assistant
Denise Young	HJF	01/15/94	NA	PT	Pathology Technician
Roger Connelly, MS	HJF	09/19/94	NA	PT	Biostatistician
Kekule Asgari	HJF	10/01/94	NA	FT	Research Physician
Carolyn Craig	HJF	12/05/94	NA	FT	Research Technician
Li Wu	HJF	08/16/95	NA	FT	Research Technician
Axel Heidenreich	German Gov't	08/01/95	NA	FT	Research Physician
Bridgit Heidenreich	Volunteer	11/01/95	NA	PT	Research Physician
Angela Pinto	HJF	10/14/95	NA	FT	Clinical Database Researcher
Howard Heidenberg, MAJ, MC	Military	07/01/93	NA	PT	Urology Research Resident
Michael Finger, MAJ, MC	Military	07/01/93	NA	PT	Urology Research Resident
Thomas Douglas, CPT, MC	Military	07/01/94	NA	PT	Urology Research Resident
John Bauer, MAJ, MC	Military	07/01/94	NA	PT	Urology Research Resident
Marie Bettencourt, CPT, MC	Military	07/01/95	NA	PT	Urology Research Resident
Ted Morgan, CPT, MC	Military	07/01/95	NA	PT	Urology Research Resident
Robert Wheelock, PhD	HJF	09/01/95	NA	FT	Molecular Biologist

b) Programs/Projects

1. Prostate Cancer Clinical Database

A major CPDR initiative continues to be the collection of demographic, medical, pathologic, and outcomes data on all prostate cancer patients treated at WRAMC and to expand this collection to other DoD health care facilities. The project has a retrospective component (collecting data on all patients treated at WRAMC since 1980), and a prospective component focusing on complete data collection of all patients seen since 1 January 1994. This project has been approved by the

Department of Clinical Investigation (DCI) at WRAMC and copies of current data collection forms are attached as Addendum

1. The forms have been used both for patient care progress notes and for CPDR data collection. Hard copy research files have been established for over 2500 patients and are housed in the CPDR office at WRAMC. Data entry with quality assurance and security precautions are utilized to enter data into a relational database with database support assistance from WRAMC. WRAMC is the alpha-site for this clinical data collection and the system will be exported to other DoD facilities for similar data collection. During this reporting period Madigan Army Medical Center (Site coordinator: Brantley Thrasher, MAJ, MC, USA); Wilford Hall USAF Medical Center (Site coordinator: Paul Friedrichs, MAJ, MC, USAF) and National Naval Medical Center (Harold Frazier, CDR, MC, USN) had the CPDR Database protocol approved by their respective Institutional Review Boards and began collecting standardized data on PC patients. In addition, Brooke AMC, Malcolm Grow USAF Medical Center, Dewitt ACH, Kimbrough ACH and San Diego Naval Hospital have all agreed to join the project. Madigan AMC has been chosen as the Beta-site and will be the first center to link up to CPDR via the Internet. During this third year of operation, CPDR has seen the database initiative show benefit. Sufficient numbers of patients have been entered into the database such that research reports can be generated and are meaningful. For example, we have analyzed all PC patients treated at WRAMC between 1990-1994 with emphasis on PC in African American men. An important research study examining prostate-specific antigen (PSA) and tumor volume in black males was published in an October 1995 issue of the prominent Journal of the American Medical Association. As more patients from multiple sites

are entered, this research database will be a valuable national resource.

2. Prospective Prostate Cancer Tissue Collection Project

In collaboration with the AFIP, all radical prostatectomies performed for prostate cancer at WRAMC are processed for CPDR research per a WRAMC DCI-approved protocol. AFIP pathology personnel come into the operating room and immediately collect fresh prostate cancer tissue and snap-freeze it for future molecular study. A strict protocol is followed for whole-mounting of the specimens for pathologic research studies. Multicentricity and volume of the tumor are determined, and tissue sections are processed for various immunohistochemical studies. As of the end of this report period, over 150 prospective specimens have been collected and cataloged. These tissues serve as the basis for CPDR laboratory studies at USUHS. Recently CPDR began collecting a portion of prostate tumor from each case for short-term cell culture and gene-therapy studies. These valuable tissues have already led to important discovery. We have been able to find racial disparity in prostate cancer volume in black and white men undergoing radical prostatectomy. Even in the equal-access US Military health-care system, African American men had larger tumors and more adverse pathologic features. Investigation is ongoing.

3. CPDR Molecular Biology Laboratory

The ongoing initiative at USUHS is involved in the study of oncogenes, tumor suppressor genes, and other molecular markers and factors in prostate cancer and benign prostate diseases. The following is a listing of ongoing projects:

a. **Alterations of cell cycle check-point (ccc) genes in prostate cancer.**

Cell cycle check-point control appears to provide control points within the cell cycle

and that appears to play a key role in maintaining the integrity of the cellular genome. Since mutational events represent one of the key molecular defects in the genesis of human cancer, our group has been studying the possible molecular defects of some ccc genes: p53, p16 and WAF/Cip1 in prostate cancer.

a-1. P53 tumor suppressor gene - a survey of tumor suppressor gene p53 mutations in various stages of prostate cancer utilizing immunohistochemistry and gene sequencing has been completed and has been published during the reporting period (Heidenberg, et al. - see below). Our studies have shown the involvement of p53 gene alterations in a high fraction of hormone refractory prostate cancer. More importantly, we have shown that the measurement of alterations of p53 in the primary tumor is a useful prognostic marker to predict recurrences after radical prostatectomy (Bauer, et al. - see below). This work with p53 has been expanded by also examining for bcl-2 oncogene expression to determine if the combination of biomarkers are of prognostic value. In a very important study of 175 men, p53 and bcl-2 were both of prognostic value to predict cancer recurrence after surgery (Bauer, et al. - see below).

a-2. p16 Gene

The p16 (MTS1) gene product is a negative regulator of the cell cycle and has been shown to be deleted or mutated in a number of tumor cell lines and primary tumors. There has been no comprehensive study of p16 gene alterations in prostate cancer. To determine the status of the p16 gene in human prostate cancer, metastatic prostate cancer cell lines and microdissected

primary tumor specimens and adjacent normal tissues from prostate cancer patients were analyzed. Although a point mutation in p16 coding sequence was detected in a metastatic prostate cancer cell line, we did not find mutations of the p16 protein coding sequence in primary prostate cancer specimens (see below Gaddipati et al.). The absence of mutation in p16 protein coding sequence in prostate cancer specimens and a low frequency of p16 mutation in metastatic cell lines suggest that such p16 alterations do not play a major role in the genesis of primary prostate cancer. However, using a new microsatellite marker, microdeletions of p16 gene locus are reported in about 50% prostate cancer and such studies are ongoing using in situ analysis for p16 gene in both primary and metastatic cancer specimens.

b. **Elucidation of molecular mechanisms involved in hormone refractory prostate cancer.**

Androgen Receptor (AR) mutations in prostate cancer - earlier work by CPDR had suggested a mutational hot spot in the AR gene may be common in advanced prostate cancer. Later work, however, failed to show AR mutations in a larger cohort of over one hundred samples. These later findings will be the basis of a research publication during the fourth reporting period. Since AR mediated signal transduction plays a critical role in prostate cell proliferation and differentiation, we initiated a project evaluating alternative mechanisms of activation of the AR signalling pathway. The ongoing experiments will characterize the role of interactions of tyrosine kinase growth factor receptor and the androgen receptor.

c. **Development of gene therapy strategies based on the molecular genetic alterations in prostate cancer.**

p53 gene therapy of prostate cancer:

In collaboration with Dr. Prem Seth (Medicine Branch NIH), we have developed adenovirus vectors containing the tumor suppressor gene p53. We have obtained very exciting results in demonstrating that adenovirus p53 vectors have dramatic inhibitory effects on the growth of metastatic prostate cancer cell lines via induction of cellular p53 pathways (Srivastava, et al see below.) Further studies in the nude mouse animal model of prostate cancer have shown significant growth inhibitory effects (60-80%) in the progression of established tumors. Further studies of antitumorigenic effects of the adenovirus p53 vector in immune competent animals are currently in progress. Additional studies are also in progress to follow up these observations in animal models and to design strategies for clinical trials. For this research, the CPDR has received a Research Award from the Association for the Cure of Cancer of the Prostate (CaP Cure) which was used to support ongoing studies during this reporting period.

d. **Development of primary cell culture from prostate tumor specimens**: We have established protocols for growing normal and prostate tumor derived cultures of epithelial cells. This work is extremely important for studies which require a pure population of tumor cells. This study also has utility for future testing of antitumor agents as there are very few prostate cancer cell lines available. We have also recently shown the cell growth inhibitory effects of the adenovirus p53 vector on primary

prostate cell cultures of four patients who underwent radical prostatectomy.

3. Development of DNA/RNA bank from prostate cancer specimens.

As an ongoing function of the CPDR molecular biology laboratory, we have now prepared DNA specimens of carefully microdissected tumor and normal tissue sections from over fifty patients who had undergone radical prostatectomy at Walter Reed Army Medical Center. These specimens represent a long term resource for molecular characterization of prostate cancer. Additionally, we have prepared DNA and RNA from blood from over 90 patients which will be used as a source of constitutional or germ line DNA for determining genetic risk factors specifically in the African American population.

4. Research projects involving collaborations with outside researchers/institutions.

a. RT-PCR of PSA gene to assess occult micrometastasis in prostate cancer. A VA research grant with the University of Washington, Seattle, and the Seattle VA Hospital was approved for $65,000 for two years and work started during this reporting period. A total of 85 peripheral blood samples and 40 bone marrow samples have been collected for this project during the reporting period. Analysis and clinical correlation of results are in progress.

b. Neural Network artificial intelligence computer programs to assess prostate cancer using clinical variables from the CPDR database. Collaboration with Kaman Sciences Corporation is ongoing to predict outcomes of CaP patients based on pre-treatment clinical and pathologic variables. The current model uses 38 input clinical and pathologic variables to predict cancer recurrence after radical prostatectomy. In a

study group of approximately 220 patients, the model was able to correctly predict recurrence with approximately 90% accuracy. This model is currently being validated in a prospective manner.

c. Cathepsin-D and EGFR expression in prostate cancer as prognostic markers. Collaboration with Medical College of Virginia and University of North Carolina. (One publication [see Maygarden, et al.], and a final report-second publication in press in the Journal of Urology [see Moul, et al.]).

d. IGFII Receptor alterations in prostate cancer. Collaboration with Duke University Medical Center (ongoing).

e. TGFB Receptor mutation and microsatellite instability in prostate cancer. Collaboration with National Cancer Institute, NIH Bethesda (ongoing).

f. Prostate specific membrane antigen (PSMA) marker studies collaboration with Dr. Gerald Murphy, Pacific Northwest Cancer Institute, Seattle, WA. Ongoing research to determine the value of this serum marker in prostate cancer patients (see Douglas, et al.).

g. Free PSA studies collaboration with Dr. Gerald Murphy (see above). Studies of prostate cancer patients to determine the value of measuring the free, unbound PSA in the serum versus the bound and total PSA concentrations.

h. Clinical trials with Eastern Cooperative Oncology Group (ECOG) at WRAMC.

CONCLUSIONS

The Center for Prostate Disease Research (CPDR) program project has made significant progress in the third year of operations. Our mission to advance knowledge of prostate cancer and disease and to integrate clinical and basic science projects is continuing and expanding. The main advances during this reporting period have been the growth, maturity, and output of the CPDR clinical database, the studies of the p53 gene and other genetic alterations in prostate cancer, development of gene therapy experiments, and the general growth solidification of our program as a national resource for the study for prostate disease.

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13. Glajchen, M, and Moul, JW:Teleconferencing as a method of educating men about managing advanced prostate cancer and pain. J Psychosocial Oncol, (in press).

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B. PUBLISHED ABSTRACTS CPDR during reporting period:

1. Moul, JW, Connelly, RR, Harris, JA, Mooneyhan, RE, Srivastava, SK, and McLeod, DG:Prostate specific antigen (PSA) values at initial prostate cancer diagnosis are higher in African-American men:Multivariable analysis of 541 patients.s Proc Am Assoc Ca Res, 36:644, 1995 (abstract No 3836)

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Urology Clinic-WRAMC

DIVISION: WALTER REED AMC
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REGISTRATION

Patient Rank: Officer Enlisted **Marital Status**: Single Married Divorced Widowed Unk

Ethnic Origin: African-American Caucasian Asian Hispanic Other:_____

Height:_____ft. _____in.

Weight:_____lbs.

PATIENT MEDICAL HISTORY:

Family History of CAP? No Yes Unk
# of 1st degree affected:_____
(Father, Brother, Son)
# of 2nd degree affected:_____
(Grandfather, Uncle, Cousin)
Alcohol Use: Current Past Never Unk
Cigs: Current Past Never Unk
Pipe: Current Past Never Unk
Cigars: Current Past Never Unk

Pre-tx Potency: No Yes Unk
Treated BPH: No Yes Unk
Treatment of BPH (Check all that apply):
☐ Alpha Block
☐ 5 Alpha Reductase
☐ Surgery
☐ Other:_____
Vasectomy: ☐ No ☐ Yes ☐ Unk
Age: ☐ < 30 ☐ 30-34 ☐ 35-40 ☐ > 40

COPD: No Yes Unk
CAD: No Yes Unk
HTN: No Yes Unk
CVA: No Yes Unk
Renal Insuf.: No Yes Unk
Diabetes: No Yes Unk
Other Cancer: No Yes Unk
Specify:_____.

GU SYMPTOMS: Yes No

Prostatism: No Yes Unk
Prostatitis: No Yes Unk
SX of Metastases: No Yes Unk
Hematospermia: No Yes Unk
Gross Hematuria: No Yes Unk

REASON FOR BIOPSY:

ABN DRE: No Yes Unk
Elev. PSA: No Yes Unk
PSA Velocity: No Yes Unk
Other: No Yes Unk
Specify:_____.

BIOPSY RESULTS:

Diagnosis Date: D_____M_____Y_____.

Number of Biopsies:_____. Number of Pos Biopsies:_____.
Previous Biopsy: No Yes No.:_____.
Previous Trus: No Yes No.:_____.
Biopsy Performed at: WRAMC Other:_____.

Location of Pos Biopsy **(Worst grade, worst gleason sum)**:
LEFT SIDE: Neg Pos Not Done
Grade: W M P Gleason Sum:_____
RIGHT SIDE: Neg Pos Not Done
Grade: W M P Gleason Sum:_____
UNKNOWN SIDE: Neg Pos Not Appl.
Grade: W M P Gleason Sum:_____

Specific Location (if known):
L. Apex L. Mid L. Base L. SV
R. Apex R. Mid R. Base R. SV

BIOPSY TYPE (Circle):

1 TRUS-Findings: Neg Pos Unk
2 Vol:_____ cc's
3 Digitally-Directed Transrectal
4 TURP
5 Other/Specify:

PRE-BIOPSY PSA:_____ **M**_____**D**_____**Y**_____.

SOAP NOTE:

Patient Name: _____SSN: _____Date of Birth: D_____M_____Y_____.

Current Address: _____.

Home Phone: _____Work Phone : _____.

Date:_____ Physician's Signature:_____Revised 12/95

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Urology Clinic-WRAMC

DIVISION: WALTER REED AMC
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STAGING

PRETREATMENT LAB VALUES (Check all that apply or enter value if known):

Creatinine:_____ D_____M_____Y_____. Alk Phosphatase:_____ D_____M_____Y _____.

Testosterone:_____ D_____M _____Y _____. Pre-Tx PSA:_____ D_____M_____Y_____.

Pre-Tx PAP:_____D_____M_____Y_____.

RADIOLOGY:

Bone Scan:	Neg	Pos	ND	Pending
MRI-Pelvis:	Neg	Pos	ND	Pending
MRI-Transrectal:	Neg	Pos	ND	Pending
CT Scan ABD:	Neg	Pos	ND	Pending
CT Scan Pelvis:	Neg	Pos	ND	Pending
CXR:	Neg	Pos	ND	Pending
IVP:	Neg	Pos	ND	Pending
CYSTO:	Neg	Pos	ND	Pending

FINAL CLINICAL STAGE (PRE-TREATMENT):

A1	C1
A2	C2
B0	C3
B1	D0
B2	D1
	D2

FINAL TNM STAGE (PRE-TREATMENT):

T1a	T3a	NX	MX
T1b	T3b	N0	M0
T1c	T3c	N1	M1
T2a	T4a	N2	
T2b	T4b	N3	
T2c			

PRIMARY TREATMENT:

Prostatectomy Hormonal Radiation Watch Wait Cryo Decision Pdg

SOAP NOTE:

Patient's Name:_____ Last Four:_____ Physician's Signature:_____.

Revised 12/95

Patient's Name:_____ Last Four:_____ Physician:_____.

RADICAL PROSTATECTOMY
PELVIC LYMPHADENECTOMY

Date of Surgery: Day _____Month_____Year_____.

Lymphadenectomy Only: No Yes

Operation Time: (Prostatectomy) Hours_____Minutes_____.

Lymphadenectomy: Open Laparoscopic Not Done

Type: Retropubic Perineal Not Done-Aborted

Nerve Sparing: Unilateral Bilateral Not Done Unk

HCT: Pre-Op_____Day_____Month_____Year_____.

Post-Op (first value on post op day 1)_____.

Autologous Blood Collected: No Yes Unk

# of Units_____.

Estimated Blood Loss (during surgery):_____cc's

Transfusion Units (intraoperative): AUTO_____ Non AUTO_____.

Was Preoperative Hormone Manipulation Used? No Yes Unk

Type (Circle): Flutamide Proscar

Lupron Zoladex

Other:_____.

Duration (weeks):_____.

Comments:

WRAMC

Revised 11/94

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PROSTATE RADIATION TREATMENT SUMMARY

Last Name:_____ First Name:_____ MI:_____ SSN:_____.

Date of Birth: D_____ M_____ Y_____ Diagnosis: Prostate Cancer Histology: Adenocarcinoma.

Gleason Sum:_____. Stage: T_____ N_____ M_____.

Tx prior to radiation therapy:

☐ From Biopsy ☐ Prostatectomy

Pre-treatment Lab Values: PSA_____.

☐ From Surgery PAP_____. ☐ Hormonal Therapy

TREATMENT:	Start Date: D_____ M_____ Y_____. Completion Date: D_____ M_____ Y_____.	Elapsed Days_____. (include start and stop date)	# of Fractions:_____. Fraction Size:_____cGy

Field Arrangement:
- ☐ 4 Field
- ☐ Arc
- ☐ Other Specify:

Energy:
- ☐ ≤10 MV
- ☐ >10 MV
- ☐ Mixed

Prescribed Dose:	Field:	Size:
Pelvis:_____cGy	_____	_____ _____._____x_____ _____._____
	_____	_____ _____._____x_____ _____._____
Prostate + SV:_____cGy	_____	_____ _____._____x_____ _____._____
	_____	_____ _____._____x_____ _____._____
Prostate:_____cGy	_____	_____ _____._____x_____ _____._____
	_____	_____ _____._____x_____ _____._____

TREATMENT RESPONSE:

Rectal SX: ☐ Diarrhea ☐ Other ☐ Proctitis	Management:
G-U SX: ☐ Frequency ☐ Dysuria ☐ Hematuria ☐ Other	Management:
Skin SX: ☐ No ☐ Yes	Management:
Breaks in Treatment: ☐ No ☐ Yes	Describe:

Px to RTC in _____weeks.

Physician Signature:_____.

Revised 1/95

HORMONAL THERAPY

ORCHIECTOMY: No Yes **Date:** D_____ M_____ Y_____.

Total:	No	Yes	Unk
Subcapsular:	No	Yes	Unk
Testicular Prostheses:	No	Yes	Unk

LH-RH: No Yes **Date Started:** D_____ M_____ Y_____. **Date Terminated:** D_____ M_____ Y_____.

Type (Circle): Lupron Zoladex Other:_____.

ANTIANDROGEN: No Yes **Date Started:** D_____ M_____ Y_____. **Date Terminated:** D_____ M_____ Y_____.

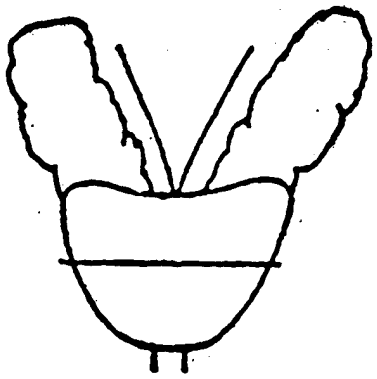
Type (Circle): Flutamide Other:_____.

Clinical Trial Tx: No Yes **Date Started:** D_____ M_____ Y_____ **Date Terminated:** D_____ M_____ Y_____.

Specify: _____.

Hormonal Failure Therapy:	No	Yes	Date Started: D_____ M_____ Y_____.	
Antiandrogen Withdrawal:	No	Yes	Unk	
Suramin:	No	Yes	Unk	
Chemotherapy:	No	Yes	Unk	If Yes, Specify:_____.
Other:	No	Yes	Unk	If Yes, Specify:_____.

SOAP NOTE:



Patient's Name:_____ Last Four:_____ Physician's Signature:_____.

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Personal Data - Privacy Act of 1974 (PL 93-579)
Urology Clinic - WRAMC

DIVISION: WALTER REED AMC
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CPDR CYROTHERAPY TREATMENT SUMMARY

I. Primary Therapy: (If primary, complete registration and staging forms and skip section II)

Date of Procedure: M_____D_____Y_____. Pre-Cryo PSA_____ Date: M_____D_____Y_____.

Pre-Cryo Lymphadenectomy: ☐ Yes ☐ No If yes, Date: M_____D_____Y_____.

If yes: ☐ Open ☐ Laparoscopic

Pre-Cryo Hormonal Therapy: ☐ Yes ☐ No

If yes, type: ☐ Lupron ☐ Zoladex ☐ Flutamide ☐ Casodex ☐ Other:

If yes, duration: _____mos.

II. Failure Therapy: Yes No

Specify FAILED XRT: ☐ Yes ☐ No (If failed XRT, complete XRT forms for 1° XRT)

FAILED Other: ☐ Yes ☐ No Specify:_____.

Recurrence Biopsy: ☐ Yes ☐ No Date: M_____D_____Y_____.

Number of Cores:_____Number of Pos Cores:_____.

Biopsy Performed at: WRAMC Other:_____.

Location of Pos Biopsy (**Worst Grade, Worst Gleason Sum**): Specific Location (if known):

LEFT SIDE: Neg Pos Not Done L.Apex L.Mid L.Base L.SV

Grade: W M P Gleason Sum:_____ R.Apex R.Mid R.Base R.SV

RIGHT SIDE: Neg Pos Not Done

Grade: W M P Gleason Sum:_____

UNKNOWN SIDE: Neg Pos Not Appl.

Grade: W M P Gleason Sum:_____

BIOPSY TYPE (Circle):

1 TRUS-Findings: Neg Pos Unk

2 Digitally-Directed Transrectal

3 TURP

4 Other/Specify:_____.

III. Cryo Procedure

Length (induction of anesthesia to leaving OR)_____HR_____MIN

Prostate Volume:_____cc Number of Insertion Sites (Circle): 2 3 4 5 6 7

Operative Complication: ☐ Yes ☐ No If Yes, Specify:_____ Double Freeze Apex: ☐ Yes ☐ No

_____ Double Freeze Base: ☐ Yes ☐ No

Surgical Notes: ☐ Yes ☐ No If Yes, Specify:_____ Pull Back: ☐ Yes ☐ No

_____.

Patient Name:_____

Current Address:_____.

_____

Home Phone:_____Work Phone:_____

Date of Birth: M_____D_____Y_____.

Date:_____

Physician's Signature:_____.

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DIVISION: WALTER REED AMC
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PROSTATE ULTRASOUND TRUS REPORT

Date of TRUS: D_____M_____Y_____ Examiner/Physician:_____

REASON FOR TRUS:

☐No ☐Yes Protocol:_____

☐No ☐Yes Elevated PSA; specify Pre-Biopsy PSA_____ D_____M_____Y_____

☐No ☐Yes PSA Velocity

☐No ☐Yes Abnormal DRE (check all that apply): Location: ☐L. Apex ☐L. Mid ☐L. Base ☐L. SV ☐Asymmetry

☐R. Apex ☐R. Mid ☐R. Base ☐R. SV

Presumptive DRE Stage: ☐B0/T1c ☐B1 ☐B2 ☐C

☐No ☐Yes Other, specify:_____

TRUS BIOPSY:

☐No ☐Yes Biopsy Performed: Location: ☐L. Apex ☐L. Mid ☐L. Base ☐L. SV ☐L. TZ

☐R. Apex ☐R. Mid ☐R. Base ☐R. SV ☐R. TZ ☐Other

Total Number of Cores:_____

TRUS FINDINGS:

☐No ☐Yes Abnormal Lesion Location (check all that apply): ☐L. Apex ☐L. Mid ☐L. Base ☐L. SV

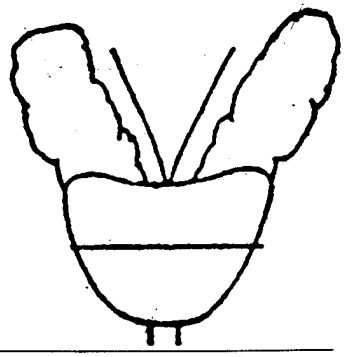
☐R. Apex ☐R. Mid ☐R. Base ☐R. SV

Volume:_____cc's PSA-D:_____ ☐Calculi ☐Hypoechoic Nod. ☐Hyperechoic Nod. ☐Isoechoic Nod.

☐No ☐Yes Previous Biopsy #_____. Capsule: ☐Intact ☐Penetrated ☐Suspicious

☐No ☐Yes Previous TRUS #_____.

SOAP NOTE:



☐ No ☐ Yes Antibiotic Prophylaxis, specify:_____

Patient Identification:

Follow-up (check one):

☐ Patient to call MD

☐ MD to call Patient

☐ Patient to make F/U Appt.

Final Path:

CA: ☐ No ☐ Yes

PIN: ☐ No ☐ Yes

Physician's Signature:_____.

Revised 4/95

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Urology Clinic-WRAMC

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PROSTATE CANCER FOLLOW-UP

Follow-up Date: D_____M_____Y_____ Protocol: No Yes _____.

New Address : N Y Specify:_____.

New Phone: N Y Specify:_____.

REASON FOR FOLLOW-UP (CIRCLE ALL THAT APPLY)

Rad. Pros. XRT HT CRYO Watchful Waiting Routine Problem, If so specify:_____.

RECURRENCE:

First Serologic (PSA) Elevation Recurrence: ☐ No ☐ Yes

Date of Recurrence: M_____D_____Y_____.

First Clinical Recurrence: ☐ No ☐ Yes

Date of Recurrence: M_____D_____Y_____.

First Clinical/Serologic Recurrence RX (Circle)

Hormonal Radiation Chemo

Watchful Wait Cryo Other:_____.

Type of First Clinical Recurrence:

Pos Bone Scan: ☐ No ☐ Yes

Local Recur.: ☐ No ☐ Yes

Visceral Mets: ☐ No ☐ Yes

LABS:

PSA:_____ M_____D_____Y_____.

PAP:_____ M_____D_____Y_____.

HCT:_____ M_____D_____Y_____.

CR:_____ M_____D_____Y_____.

ALK PHOS:_____ M_____D_____Y_____.

TESTOS:_____ M_____D_____Y_____.

Second Recurrence: ☐ No ☐ Yes Date: M_____D_____Y_____ Specify:_____.

CONTINENCE/POTENCY:

Continence: ☐ No ☐ Yes

If no, number of pads/day:_____

If yes, month/year continent: M_____Y_____

Potency: ☐ No ☐ Yes

If no, circle Tx: VET ICI Penile Pros None Other:_____.

COMPLICATIONS OF PRIMARY TREATMENT: ☐ **No** ☐ **Yes**

If Prostatectomy:

DVT/PE: ☐ No ☐ Yes ☐ Unk

MI/Cardiac: ☐ No ☐ Yes ☐ Unk

Rectal Injury: ☐ No ☐ Yes ☐ Unk

BN Contracture: ☐ No ☐ Yes ☐ Unk

Reoperation: ☐ No ☐ Yes ☐ Unk

Specify:_____

Other: ☐ No ☐ Yes_____

If Hormonal:

Hot Flashes: ☐ No ☐ Yes ☐ Unk

Diarrhea: ☐ No ☐ Yes ☐ Unk

Surgical: ☐ No ☐ Yes ☐ Unk

Gynecomastia: ☐ No ☐ Yes ☐ Unk

Antiandrogen Stopped: ☐ No ☐ Yes ☐ Unk

Other: ☐ No ☐ Yes_____

If Radiation:

GI Symptoms: ☐ No ☐ Yes ☐ Unk

Specify:_____.

GU Symptoms: ☐ No ☐ Yes ☐ Unk

Specify:_____.

PSA Nadir: _____.

D_____M_____Y_____.

If Cryotherapy: ☐ No ☐ Yes ☐ Unk If yes, specify:_____.

SOAP NOTE:

Current Clinical Stage:_____. Disease Status (Circle): NED Alive w/CAP Alive/Unk

Patient's Name:_____ Last Four:_____Physician's Signature:_____Revised 12/95

WALTER REED ARMY MEDICAL CENTER
Personal Data - Privacy Act of 1974 (PL 93-579)

DIVISION: WALTER REED AMC
Automated Version of SF 600

PROSTATE RADIATION THERAPY FOLLOW-UP

Name:_____ SSN:_____

Radiation Dose:_____cGy Completion Date: D____M____Y____

Original Stage: T_____N_____M_____

PSA: Pre-treatment:_____ Current:_____

Prostatectomy: ☐ No ☐ Yes Date: D____M____Y____

Past Hormonal Therapy: ☐ No ☐ Yes Currently: ☐ No ☐ Yes

Orchiectomy: ☐ No ☐ Yes Date: D____M____Y____

Hormone Failure: ☐ No ☐ Yes

INTERVAL HISTORY (Constitutional Complaints):

Weight Loss: ☐ No ☐ Yes Fatigue: ☐ No ☐ Yes Night Sweats: ☐ No ☐ Yes Febrile Episodes: ☐ No ☐ Yes

Bone Pain: ☐ No ☐ Yes Site of Bone Pain:_____

GASTROINTESTINAL SYMPTOMS:

Constipation: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

BRBPR: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Stool Incontinence: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Melena: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Rectal Pain: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Diarrhea: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

stools/day_____

GENITOURINARY SYMPTOMS:

Hematuria: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Urinary Frequency: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Dysuria: ☐ No ☐ Yes ☐ Daily ☐ Weekly ☐ Monthly ☐ Less

Nocturia: ☐ No ☐ Yes Frequency (Episodes/night)_____

Decreased Erectile Function: ☐ No ☐ Yes

Erections: ☐ Normal ☐ Partial ☐ None

Incontinence: ☐ No ☐ Yes Pads/day: ☐ One ☐ > One

PHYSICAL EXAM:

Vital Signs: Temp:_____ Pulse:_____ Wt:_____

Resp:_____ B/P:_____

Lymphadenopathy:_____

_____

Abdomen:_____

_____

Musculo-skeletal:_____

_____

Rectal: Tone:_____ Guaiac:_____

Prostate:_____

_____

FOLLOW-UP & DISPOSITION:

Disease Status:

NED: ☐ No ☐ Yes

PSA: ☐ Rising ☐ Falling ☐ Stable

Clinical Response: DRE: ☐ Normal ☐ Stable ☐ Better ☐ Worse

D.M.: ☐ No ☐ Yes

Orders:_____

Physician's Signature:_____

Date: D_____M_____Y_____

Revised 1/95

CPDR NECROPSY FOLLOW-UP FORM

DEATH INFORMATION

DATE OF DEATH: D_____M_____Y_____.

PLACE OF DEATH: _____CITY_____STATE

DEATH CERTIFICATE ATTACHED: ☐ Yes ☐ No

IF NO, PLEASE PROVIDE CONTACT FOR CPDR TO WRITE FOR CERTIFICATE: _____

_____

_____.

CAUSE OF DEATH (Please Check):

☐1 **FROM PROSTATE CANCER**

☐2 **FROM OTHER CAUSE, Specify**_____.

If other cause, was Prostate Cancer present at death: ☐ **Yes** ☐ **No**

If Yes, Stage of Prostate Cancer at death:

FINAL CLINICAL STAGE	
A1	C1
A2	C2
B0	C3
B1	D0
B2	D1
	D2

FINAL TNM STAGE			
T1a	T3a	NX	MX
T1b	T3b	N0	M0
T1c	T3c	N1	M1
T2a	T4a	N2	
T2b	T4b	N3	
T2c			

☐3 **CAUSE OF DEATH UNKNOWN**

SOAP NOTE:

Patient's Name:_____ Last Four:_____ Physician's Signature:_____.

RADICAL PROSTATECTOMY PATHOLOGY

Primary Hospital Path. Accession Number:_____.

AFIP Referral: Yes No **AFIP Accession Number:**_____.

OVERALL: (Circle Correct Answers)

Capsule	Negative MicroInv. Infilt. Equivocal Unilat Bilat Unk
Margins	Negative Positive Unilat Bilat Unk
Seminal Vesicles	Negative Positive Unilat Bilat Unk
Nodes	Negative Positive Unilat Bilat Unk # of pos. nodes:_____
Worst Grade	Well Moderate Poor Unk
Worst Gleason	2 3 4 5 6 7 8 9 10 Unk
Worst Nuc. Grade	1 2 3 Unk
Urethra	Negative Positive Unk
Bladder Neck	Negative Positive Unk
Multifocal	No Yes Unk
Benign Tiss. in Margin	No Yes Unk
# of Prostatic Tumors	1 2 3 4 5 6 7 8 9 10 >10 Unk

TUMOR SIZE(cc) L W H	ORGAN CONFINED	WORST GRADE	WORST NUC GRADE	SIDE	LOCATION
1 ____x____x____	Yes No	W M P	1 2 3	L R B	A M B
2 ____x____x____	Yes No	W M P	1 2 3	L R B	A M B
3 ____x____x____	Yes No	W M P	1 2 3	L R B	A M B
4 ____x____x____	Yes No	W M P	1 2 3	L R B	A M B
5 ____x____x____	Yes No	W M P	1 2 3	L R B	A M B

Total Prostate Weight_____ grams

Final Pathological Stage: (A1) (A2) B1 B2 C C1 C2 C3 D1 D2 D0

Final TNM Pathological Stage: (T1a) (T1b) (T1c) T2a T2b T2c T3a T3b T3c T4a T4b

NX N0 N1 N2 N3

MX M0 M1

Patient's Name:_____ **SSN:**_____.